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TITLE: Development of Meharry Medical College Prostate Cancer Research Program

PRINCIPAL INVESTIGATOR: Flora A. M. Ukoli

CONTRACTING ORGANIZATION: Meharry Medical College
Nashville, TN 37208

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14. ABSTRACT

There is substantial urology, oncology, epidemiology, nutrition and other expertise at Meharry and Vanderbilt addressing issues related to prostate cancer (PCa) disparity among African-American (AA) men, and the six program new/junior minority investigators have maintained partnerships with VU mentors, and established viable community network ties. Dr. Ukoli has recruited 105 participants into the lycopene study, sent 192 stored plasma samples for lycopene analysis, and received a DHHS 2-year funding for prostate cancer education intervention among low-income AAs. Dr. Washington recruited 200 participants into the PCa health care seeking behavior study, is now analyzing the data, and preparing a full grant proposal. Dr. Stewart completed her pilot project, received independent funding to continue her PCa cell line studies, two of her students received pre-doctoral awards, and will apply for a CTSA grant for DNA extraction/genotyping to investigate genetic polymorphisms in PCa risk using 300 AA and Nigerians samples storedby Dr. Ukoli. Dr. Ogunkua's work continues to grow; he has now dosed/sacrificed 60 mice recording data at all time-points, and submitted one R21. Dr. Taher is revising his DOD career development grant that scored 2.5, presented two posters, and currently working on a manuscript with the PI.

15. SUBJECT TERMS
Prostate cancer, Dietary risk factors, Lycopene, Genetic predisposition, African-Americans, Cancer research training, Quality of life, Community outreach, Recruiting study participants, Cell line inhibition, Animal studies, Prostate cancer screening.

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INTRODUCTION:

[Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.]

The reason for African-Americans (AA) being disproportionately affected by prostate cancer (PCa) may include biologic tumor differences, genetic predisposition, differential exposures, limited utilization of preventive health care such as prostate specific antigen (PSA) testing, and inadequate access to health care. The paucity of minority PCa investigators and low accrual of AAs in clinical trials also contribute to the lack of progress in reducing this disparity. This proposal includes research initiatives to study the genetics, pathogenesis and epidemiology of PCa disparity among AA men. The genetic similarity between AAs and Africans, disparity in the degree of racial admixture, differences in dietary style and body fat patterns provide the unique opportunity to study genetic and environmental causes of PCa in black men. The PCRP now has 9(75%) members of its initial membership at Meharry, all three collaborators at the University of Benin in Nigeria, and each of the pilot project PIs at Meharry continue to retain there mentors/collaborators at VUMC, working on overlapping PCa topics at the genetic, molecular, clinical and epidemiological levels.

The program goals are to:

1). Develop an Outreach Core to sustain communication network with AA communities in Nashville, address PCa needs and facilitate recruitment into PCa early detection programs and research studies.

2). Develop a PCa research training program for junior faculty, new PCa investigators, and graduate students.

3). Conduct pilot projects, accumulate preliminary data, submit independent proposals, and generate new research ideas to sustain the PCRP at the completion of this DOD award.

The scientific aims of the program are to:

1). Conduct research of biomarkers and lifestyle risk factors of PCa development and progression in African-Americans and Africans.

2). Study the role of specific genes, gene-gene interactions, gene-environment interactions in PCa initiation and progression in these populations.

3). Conduct investigator-initiated clinical trials with emphases on nutritional interventions and molecular therapeutics.

4). Use mass spectrometry and proteomic-based approaches to identify predictive factors of PCa aggressiveness, treatment response and metastasis and develop molecular classifications and/or biomarkers of aggressive PCa.

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BODY:

*[This section of the report shall describe the research accomplishments associated with each task outlined in the **approved** Statement Of Work. Data presentation shall be comprehensive in providing a complete record of the research findings for the period of the report. Appended publications and/or presentations **may** be substituted for detailed descriptions but **must** be referenced in the body of the report. If applicable, for each task outlined in the Statement of Work, reference appended publications and/or presentations for details of result findings and tables and/or figures. The report shall include negative as well as positive findings. Include problems in accomplishing any of the tasks. Statistical tests of significance shall be applied to all data whenever possible. Figures and graphs referenced in the text may be embedded in the text or appended. Figures and graphs can also be referenced in the text and appended to a publication. Recommended changes or future work to better address the research topic may also be included, although changes to the original Statement of Work **must** be approved by the Grants Officer. This approval must be obtained prior to initiating any change to the original Statement of Work.]*

Statement of Work:

Completed Tasks

Task 1: Start-Up Phase

The Program Executive Board remains in place to oversee the scientific merit of the program. This committee is made up of senior faculty from MMC and VUMC.

MMC Faculty	VUMC Faculty
Derrick Beech, MD.	Robert Matusik, Ph.D.
Flora A. M. Ukoli, MD, MPH.	Rodney Davis, MD.
Margaret Hargreaves, Ph.D.	Susan Kasper, Ph.D.
Billy Ballard, DDS, MD.	Robert Dittus, MD, MPH.

The program Advisory Board continues to ensure the smooth running of the program, and is made up of senior and administrative faculty external to the program.

Lee E Limbird, PhD.	Vice President for Research, MMC. (Committee Chair)
John J. Murray, MD. PhD.	Associate Vice President for Clinical Research, MMC
Andrea Baruchin, PhD.	Assistant Vice Chancellor for Research, VUMC
Gordon Bernard, MD.	Assistant Vice Chancellor for Research, VUMC

The PI consults regularly with members of the Executive and Advisory Boards as needed. Both boards have been extremely supportive and their input has been very useful in moving this program to its present status and achievements.

Task 2. **Development of Program Outreach Core (2 – 6 months)**

The PI has maintained membership of various community networks and is still implementing the prostate cancer education program for low-income African-Americans funded by the Centers for Medicare and Medicaid Services (CMS)

Products:
Membership of numerous community organizations
Men's Health Network (MHN)
Women Against Prostate Cancer (WAPC)
Prostate Cancer Support Group (USTOO)
Jefferson Street United Merchants Partnership (JUMP)
CMS Award # 1I0CMS030208/01.

Task 3 **Initial Training: Investigators, Trainee-PIs, Post-Doc, GRA (2-8 months)**

The post-doctoral fellow (Abu K. Taher, M.D., MPH), accepted a residency training appointment in New Jersey, and a position was advertised. The trained graduate student (Mbeja Lomotey) and a second trainee (Angel Moore) are currently completing their MSPH thesis using the project database for secondary analysis.

Products:
Graduate students (3 previous, and 2 current)
Post-doctoral fellow (2 previous)

Deliverables:
Regular learning contact with respective mentors as needed.
Monthly tutorials within each pilot project team.

Task 4: **Continuing Medical Education in Prostate Cancer Research (Month 3 – 36)**

CME is ongoing within and outside the program. Each pilot project PI attends the seminars relevant to their topic and area of study.

Seminar Series Attendance:

Vanderbilt University	
Epidemiology Seminar series	(Weekly)
Urological Workshop on Research	(Weekly)
Vanderbilt Ingram Cancer Center Seminar series	(Weekly)
Meharry Medical College	
Grand rounds in surgery/Prostate cancer seminar series	(Monthly)
Grand rounds in internal medicine/Family medicine	(Monthly)

Works-In-Progress Seminar Series
Department of Cancer Biology (Weekly)
Tennessee State University
Center for Health Research TN State University (Weekly)

Attendance at Workshops and Conferences: 2008

1 Second Annual Meeting of Women Against Prostate Cancer (WAPC). Dec 5-6, 2008. Cancer Institute of New Jersey. New Brunswick NJ.

2 NIH/CRCHD Cancer Health Disparity Summit 2008. July 14 – 17, 2008. Bethesda MD.

3 Department of Defense Breast Cancer Research Program Building Networks Symposium. The Era of Hope. June 24 – 28, 2008. Baltimore, MD.

4 The Role of the Built Environment on Health Disparities: Removing Roadblocks to Healthy Communities. June 12 – 13, 2008. Millennium Maxwell House Hotel, Nashville, TN.

5 Living in Full Blossom: Celebration of Cancer Survivorship. Vanderbilt-Ingram Cancer Center. June 8, 2008. Nashville, TN.

6 Afro-Caribbean Cancer Consortium 2nd Annual International Meeting. May 12-13, Miami, FL.

7 Community Based Participatory Research (CBPR) Workshop. Nashville, TN.

8 Mathew Walker Surgical Symposium. "New Developments in Oncology". May 2, 2008. Nashville, TN.

Oral Presentations 2008:

1. Breast Feeding Practices and Programs: The Baby-Friendly Hospital Initiative: Promoting Breast Feeding in an Urban Hospital. Women's Health Center Grand Round. Meharry Medical College. Dec 3, 2008. Nashville, TN.

2. The Role of Meat, Fish and Egg Intake in Prostate Cancer Risk among Nigerians. Afro-Caribbean Cancer Consortium 2nd Annual International Meeting. May 12-13, 2008, Miami, FL.

3. Prostate Cancer Screening among African-Americans: Informed Decision Making. Presented at the Mathew Walker Surgical Symposium. "New Developments in Oncology". May 2, 2008. Nashville, TN.

4. International Collaboration in the Investigation of Prostate Cancer Dietary Risk Factors among Men of African Ancestry: Nigeria.
   A Global Health Symposium on Research: Vanderbilt University School of Medicine's Institute for Global Health. April 2, 2008. Nashville, TN.

5. Informed Decision Making about Prostate Cancer Screening among African-Americans
   Meharry Medical College Surgical Grand Round presentation: February 13, 2008. Nashville, TN.

Posters:

1. Regional Differences in Barriers to Prostate Cancer Screening among African-American Men. Kushal Patel, Margaret Hargreaves, Venita Bush, Donna Kenerson, Leah Alexander, Flora Ukoli.
   CRCHD 2008 Cancer Health Disparity Summit. Bethesda MD. July 14-17, 2008.

2. The Role of Meat, Fish and Egg Intake in Prostate Cancer Risk among Nigerians.
   Flora A Ukoli[1*], Khandaker Taher[1], Eruke Egbagbe[2], Mbeja Lomotey[1], Temple Oguike[2], Phillip Akumabor[2], Usifo Osime[2], Derrick Beech[1].
   Afro-Caribbean Cancer Consortium 2nd Annual International Meeting. May 12-13, Miami, FL.

Task 5. **Subject Recruitment and Data Collection. (6 – 36 months)**

Research Projects:

Pilot Project 1: (Dr. Ukoli, PI / Dr. Robert Dittus, Mentor) HSRRB Log No. A-13323.0

"Lycopene in Prostate Cancer Risk among African-Americans and Nigerians: A Case-Control Study"

Lycopene analysis report was received for 177 of the 192 stored samples. Some samples were not sufficient to measure the cis- and the trans- forms of lycopene and not just the simple total lycopene. (Dr. Myron Gross's laboratory

Nashville Site: HSRRB Log No. A-13323.1a (Proposal No. PC041176)

Data collection was discontinued until the urologist position at Meharry was filled. After that 4 prostate cancer cases and 15 controls were recruited, bringing the total cases to 34. Including participants in the PI's first study (DAMD17-02-1-0068) who agreed to have their samples used in future prostate cancer related studies we do have up to 205 completed food frequency questionnaire. At this time we however need to meet our recruitment goal for prostate cancer cases. New

partnership with private urologists in Nashville who see African-American patients including Rodney Davis, MD (Nashville General Hospital) and William Hughes, MD (Meharry Medical Practice) have been established.

The PI is an active member of the following community groups/associations:

a. USTOO International
b. USTOO Meharry Chapter (Fascilitator/Founder.)
c. Men's Health Network
d. Interdenominational Ministers Fellowship
e. Women Against Prostate Cancer (WAPC)
f. TN Prostate Cancer Coalition
g. NAACP, Nashville.
h. United Nashville Partners Against Cancer (UN-PAC) (Meharry-Vanderbilt-TSU Cancer Outreach partnership)
i. Jefferson Street United Merchants Partnership (J.U.M.P.), Nashville. In collaboration with JUMP a Barber's shop health education initiative is currently in its planning stage.

Nigeria Site: HSRRB Log No. A-13323.1b (Proposal No. PC041176)

51 participants were recruited in 2008, bringing the total to 204, 56 confirmed prostate cancer cases, 78 controls and 70 men with elevated PSA who have been referred to the urologist for adequate follow-up. In 2008 17 cases, 13 controls and 21 men with elevated PSA yet to be resolved by prostate biopsy were recruited into the study. Some of the prostate cancer cases who consented did not complete the study questionnaire because they were very ill, and follow-up process is ongoing. The collaboration with our colleagues at the University of Benin remains strong. Only one new urology faculty was appointed in the institution last year, and he is interested in working with the PI on future projects when funding becomes available. All investigators at this site remain supportive and interested in collaborating with the PI on this project. Approval has been received from their Research Ethical Committee allowing recruitment until October 2009.

The PI has in the process of establishing USTOO Nigeria chapter that will actively promote prostate cancer awareness in that community and improve knowledge about screening and treatment of prostate cancer.

Products:

1. Nigeria: Investigators/Collaborators in Nigeria remain supportive.
2. Nashville: Supportive urologists in Nashville:
   William Hughes, M.D. (Private/Meharry)
   Rodney Davis, M.D. (Vanderbilt / Meharry faculty)
   Ram Dasari, M.D. (Urology Associates)
3. IRB periodic reviews and approvals from MMC and UBTH.

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Deliverables:

1. Stored blood samples from 72 new participants to be analyzed.
2. 177 lycopene measurements completed.
3. Abstracts/Poster: 1 submitted and 1 accepted.
4. One manuscript under preparation.
5. Grants Submitted:
   i) R03 submitted: Prostate Cancer Education and Screening Pilot Program for African-Americans. Score 240.
   Resubmitted March 2009.
   ii) Department of Defense (DOD) Collaborative Undergraduate HBCU Student Summer Training Program Award: "Prostate Cancer Research Training in Health Disparities for Undergraduates (PCaRT)". Funded. $199,799.
   Grant # W81XWH-09-1-0161.
6. Community-based prostate cancer health education presentations 2
7. Community-based prostate cancer screening activities 1
8. MMC-based prostate cancer screening (available daily by appointment)
9. Parent Study SPSS database: Data entered for 1054 participants.
   1. Personal information/Urology symptom history
   2. Diet assessment
   3. Food Frequency
   4. Fatty acid profile
   5. Lipid profile
   6. Lycopene profile

Pilot Project 2: (Dr. Cui, PI / Dr. Robert Dittus, Mentor)

"Genetic Indices of Steroid Hormone Synthesis and Metabolism in Prostate Cancer: A Pilot Study."

Closed (See 2008 report).

Pilot project 3: (Dr. Washington PI / Dr. Robert Dittus)

"Prostate Cancer Health Care Seeking Behavior of African American Men."

Completed. (See 2008 report)

Pilot project 4: (Dr. Stewart, PI / Dr. Matusik, Mentor)

"Inhibition of Prostate Cancer Growth by Thiazolidinediones"

Completed. (See 2008 report)

Pilot project 5: (Dr. Ogunkua, PI / Dr. Matusik, Mentor)

"Benzopyrene B(a)P Induced Activation of Prostatic Specific Genes"

Completed (See 2008 report)

Pilot Project 6: (Post-Doctoral Fellow Dr. Taher / Dr. Cookson & Dr. Ukoli, Mentor)

"Racial comparison of health related quality-of-life outcomes in early prostate cancer".

Career development award was submitted but not funded so the post-doc accepted a residency position elsewhere and left. This pilot project was therefore closed. (See 2008 report for abstracts and posters developed under the mentorship of the PI).

Task 6. On-going and Final Data Analysis (Non-Cost Extension approved)

Data analysis is only in the preliminary stage given that the lycopene measures were received a few months ago.

Task 7. Report Writing and Presentations

We shall start writing reports in April 2009, and presentations will follow before the end of the year.

Task 8. Developing Grant Proposals for Independent Funding (24-36 months)

Flora Ukoli, MD., MPH. DOD: W81XWH-09-1-016 Funded.
Title: Prostate Cancer Research Training in Health Disparities for Undergraduates (PCaRT)
NIH: RO3 Resubmitted.
Title: Prostate Cancer Education Program for African-Americans

LaMonica Stewart, Ph.D. NCI/NIH 5 K01 CA114235-02 Funded.
Title: Regulation of Prostate Cancer Growth by PPAR gamma ligands

Ben Ogunkua, MD, Ph.D. R21 to NIEHS resubmitted.

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KEY RESEARCH ACCOMPLISHMENTS:

[Bulleted list of key research accomplishments emanating from this research.]

This is indeed a very ambitious program that succeeded in meeting its goal of establishing prostate cancer research projects at Meharry.

1. The prostate cancer research program (PCRP) has been established at Meharry Medical College.

2. Pilot project PIs are now involved in an HBCU summer training program where they will mentor minority undergraduates to conduct basic, translational and clinical research in the area of prostate cancer.

3. Three research teams are in place in collaboration with investigators from Vanderbilt University.

4. The international collaboration with the University of Benin, Nigeria, continues to be maintained.

5. The program has full access to three research laboratories developed by Dr. Stewart, Dr. Ogunkua, and Dr. Marshall.

6. In partnership with Derrick Beech, M.D., professor and chair of surgery and Margaret Hargreaves, Professor of medicine, community trust continues to grow as we offer prostate cancer education and screening intervention through our Community-Based Participatory Research (CBPR) grant from the CMS.

7. Graduate student exposure:
   a. Dr. Stewart's laboratory continues to support 2 doctoral students.
   b. Dr. Ukoli's project continues to support two MSPH students.

8. <u>Pilot Projects:</u>

   Pilot project 1: 70 additional participants recruited. 177 blood samples analyzed for lycopene.
   Pilot project 2: Discontinued at this time.
   Pilot project 3: Completed. Manuscript in preparation.
   Pilot project 4: Completed and PI has now secured independent funding.
   Pilot project 5: Mice colony established. New experiments to be developed.

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REPORTABLE OUTCOMES:

[Provide a list of reportable outcomes that have resulted from this research to include:]

1. Partnership established with several organizations and community groups in Nashville:
   - Interdenominational Ministers Forum (IMF)
   - 20 church communities
   - 3 local prostate cancer non-profit organizations
   - Two local African-American fraternities
   - Several community groups and organizations including
     - -100 Black Men of America.
     - -NAACP
     - -World Baptist Center
     - -Academy for Educational Development (AED)

2. Partnership with the clinical research centers at Meharry and Vanderbilt:

   i) CRC at Meharry is actively involved
   ii) GCRC at VU ready to support program with DNA extraction and genotyping.

3. Maintained partnership with the Nigerian research collaborators: Usifo Osime, (Director), Philip Akumabor and Temple Oguike (urologists), Patrick Okoro, and Obarisiagbon (junior investigators in general surgery and urologist) have indicated interest to start training.

4. Maintained strong partnerships with mentors and collaborators at Vanderbilt.

5. 4 pilot project PIs still actively involved in prostate cancer research.

6. A new PI at Meharry, Maureen Sanderson, Ph.D., has now developed a prostate cancer research grant and is collaborating with the PI.

7. 4 additional faculty from the department of surgery (Alphonse Pasipanodya, Carlton Adams, and Lemuel Dent) and from the department of medicine (Kushal Patel) have expressed interest in prostate cancer research and started working on research projects.

CHALLENGES:

PCRP Membership:

Retaining a post-doctoral fellow in this field has been a challenge, and one of the criteria for scoring a career development grant application is evidence of previous scholarly activities between the mentor and the post-doc. We did not receive approval for additional funding to support pilot project PIs at a 5-10% effort level to protect time for their pilot project, support their basic research costs, and develop a laboratory for the PI. In the absence of a laboratory at Meharry nutrient

analysis have to be completed by fee-for-service, and this is quite expensive, and beyond the PI's control.

Study Participant Recruitment:

Nashville Site:

Participant incentive was not high enough to stimulate interest. $80-$100 will probably encourage minority men who earn wages to miss a day's job to participate.

Nigerian Site:

Prostate biopsy in Nigeria: Lack of equipment for ultrasound guided biopsy continues to be a challenge.

CONCLUSIONS:

[Summarize the results to include the Importance and/or implications of the completed research and when necessary, recommend changes on future work to better address the problem. A "so what section" which evaluates the knowledge as a scientific or medical product shall also be included in the conclusion of the report.]

A program such as this will require at least one renewal to achieve its goal at the impressive level anticipated. Having gathered this amount of momentum it will be encouraging if the Department of Defense will consider requesting application for grant renewal for three-five year period. This program has successfully produced minority prostate cancer investigators who are submitting competitive research grant proposals, received additional funding, and attracting both graduate and undergraduate students. The enthusiasm of program members and mentors, and particularly of the first time program PI, must be supported either by supplemental funds or grant renewal.

Pilot Project I: The role of lycopene in prostate cancer risk among African-Americans and Nigerians: A cse-control study.

Trans-lycopene is significantly higher among African-Americans compared to Nigerians, 10.12±5.9 vs 4.99±3.7, $p<0.001$. While African-American prostate cancer cases have a much lower trans-lycopene level than their controls 7.45±41.1 vs 11.22±6.2, $p<0.006$, Nigerian cases and controls were similar. However Nigerian cases recorded lower 13-cis-lycoepene and 9-cis lycopene B in comparison with their controls, 3.02±1.8 vs 4.95±3.2, $p<0.002$, and 1.16±0.9 vs 1.74±1.2 $p<0.02$, respectively..

REFERENCES: *[List all references pertinent to the report using a standard journal format (i.e. format used in Science, Military Medicine, etc.).]*

APPENDIX A:

Pilot Project 1: Preliminary Data Analysis

The role of Lycopene in prostate cancer risk among African-Americans and Nigerians: A case-control study

Table 1 Description of the Data Base for the Lycopene Pilot Study

	Nashville Site African-Americans	Nigeria Site Nigerians	Total
From parent study	122	142	264
Recruited 2006	25	0	25
Recruited 2007	38	71	109
Recruited 2008	19	51	70
Total	204	264	468

Table 2 Status of Lycopene analysis of samples from Nashville and Nigeria study sites

Lycopene	African-Americans	Nigeria	Total
Measured	65	80	145
Not measured	139	184	323
Total	204	264	468

Table 3a Study participant case-control status by study site at recruitement

Prostate Cancer Status	Nashville	Nigeria	Total
Case	38	88	126
Control	152	114	266
Elevated PSA	8	62	70
No Blood Sample	6	0	6
Total	204	264	468

Table 3b Prostate cancer case status for African-Americans and Nigerians

Prostate Cancer Status	African-Americans	Nigerians	Total
Confirmed Case	38	88	126
Not a Case	166	176	342
Total	204	264	468

Table 4 Age distribution of African-American and Nigerian study participants

Age (years)	African-Americans		Nigerians		Total	
	n	%	n	%	n	%
< 54	108	52.9	72	27.3	181	38.5
55 - 74	90	44.1	150	56.8	240	51.3
≥ 75	6	2.9	40	15.2	46	9.8
Not recorded	0	0	2	0.8	2	0.4
Total	204	100.0	264	100.0	468	100.0

Table 5 Marital status of African-American and Nigerian study participants

Marital Status	African-Americans		Nigerians		Total	
	n	%	n	%	n	%
Single	69	33.8	2	0.8	71	15.2
Married	69	33.8	252	95.5	321	68.6
Divorced/Separated	55	27.0	5	1.9	60	12.8
Widowed	11	5.4	2	0.8	13	2.8
Not Recorded	0	0.0	3	1.1	3	0.6
Total	204	100.0	264	100.0	468	100.0

Table 6 Income status of African-American and Nigerian study participants

Income Status	African-Americans		Nigerians		Total	
	n	%	n	%	n	%
Low	118	57.8	158	59.8	276	59.0
Middle	58	28.4	36	13.6	94	20.1
High	21	10.3	10	3.8	31	6.6
Not Recorded	7	3.4	60	22.7	67	14.3
Total	204	100.0	264	100.0	468	100.0

Table 7 Education status of African-American and Nigerian study participants

Education	African-Americans		Nigerians		Total	
	n	%	n	%	n	%
Primary or less	0	0	106	40.2	106	22.6
High school/some	109	53.4	73	27.7	182	38.9
Some college	17	8.3	29	11.0	46	9.8
College/Graduate	78	38.2	41	15.5	119	25.4
Not recorded	0	0	15	5.6	15	3.2
Total	204	100.0	264	100.0	468	100.0

Table 8 Prostate status on digital rectal examination of African-Americans and Nigerians

Prostate	African-Americans		Nigerians		Total	
	n	%	n	%	n	%
Normal	122	59.8	67	25.4	189	40.4
BPH No symptoms	18	8.8	10	3.8	28	6.0
BPH with symptoms	18	8.8	88	33.3	106	22.6
Abnormal	5	2.5	54	20.5	59	12.6
Not done/recorded	41	20.1	45	17.0	86	18.4
Total	204	100.0	264	100.0	468	100.0

Table 9 Pattern of PSA for African-American and Nigerian study participants

PSA (ngs/dl)	African-Americans		Nigerians		Total	
	n	%	n	%	n	%
0.0 – 3.9	181	88.7	123	46.6	304	65.0
4.0 – 19.9	20	9.8	63	23.9	83	17.7
20.0 – 99.9	0	0	38	14.4	38	8.1
100.0 – 499.9	1	0.5	23	8.7	24	5.1
$\geq$ 500	2	1.0	17	6.4	19	4.1
Total	204	100.0	264	100.0	468	100.0

The following tables are limited to the 145 participants whose blood samples have been analyzed for lycopene.

Table 10 Prostate cancer diagnosis of African-Americans and Nigerians

Study population	Case	Control	Total
African-Americans	19	46	65
Nigerians	33	47	80
Total	52	93	145

Table 11 Socio-demographic and urology symptom history of African-Americans and Nigerians

Characteristics	African-Americans n = 65	Nigerian n = 80	p-value
Age (Years)			0.07
< 54	22 (33.8)	17 (21.3)	
55 – 74	38 (58.5)	48 (60.0)	
≥ 75	5 (7.7)	15 (18.8)	
Education Status			<0.001
Elementary or less	0 (0.0)	38 (47.5)	
High School/Some high	33 (50.8)	21 (26.3)	
Some College	8 (12.3)	7 (8.8)	
College / Graduate	24 (36.9)	11 (13.8)	
NR	0	3 (3.8)	
Income Status			0.012
Low	31 (47.7)	55 (68.8)	
Middle	26 (40.0)	13 (16.3)	
High	4 (6.2)	4 (5.0)	
NR	4 (6.2)	8 (10.0)	
Marital Status			<0.001
Single	18 (27.7)	1 (1.3)	
Married	22 (33.8)	74 (92.5)	
Separated/Divorced	21 (32.3)	4 (5.0)	
Widowed	4 (6.2)	1 (1.3)	
DRE & Urology Symptoms			<0.001
Normal	48 (73.8)	24 (30.0)	
Enlarged no Symptom	1 (1.5)	0 (0.0)	
Enlarged with Symptom	3 (4.6)	30 (37.5)	
Abnormal (Suspect PCa)	3 (4.6)	12 (15.0)	
Not Done/Recorded	10 (15.4)	14 (17.5)	
PSA Distribution			<0.001
0 – 3.9	60 (92.3)	47 (58.8)	
4.0 -19.9	4 (6.2)	4 (5.0)	
20 – 99.9	0 (0.0)	13 (16.3)	
100 – 499.9	1 (1.5)	9 11.3)	
≥ 500	0 (0.0)	7 (8.8)	

Table 12. Comparison of fasting plasma Trans- and Cis- Lycopene (µg/dl)‡ of African-American and Nigerian study participants

	Plasma Lycopene Mean±SD		
Fatty Acids	African-Americans	Nigerians	p-value
Trans-Lycopene	10.12±5.9	4.99±3.7	<0.001
13-cis-Lycopene	4.40±3.0	4.15±2.9	0.62
9-cis-Lycopene A	1.08±1.1	0.71±0.6	0.02
9-cis-Lycopene B	1.53±1.5	1.50±1.1	0.88

Table 13. Comparison of fasting plasma Trans- and Cis- Lycopene (µg/dl)‡ of African-American and Nigerian study participants

	Plasma Lycopene Median (25^{th} , 75^{th} percentile)		
Fatty Acids	African-Americans	Nigerians	p-value
Trans-Lycopene	8.77 (5.53, 13.45)	4.44 (2.14, 6.56)	<0.001
13-cis-Lycopene	3.70 (2.55, 6.03)	3.33 (2.18, 5.86)	0.53
9-cis-Lycopene A	0.72 (0.29, 1.60)	0.60 (0.35, 0.85)	0.20
9-cis-Lycopene B	1.15 (0.46, 2.27)	1.28 (0.76, 2.00)	0.59

African-Americans:

Table 14. Comparison of fasting plasma Trans- and Cis- Lycopene (µg/dl)‡ of African-American prostate cancer cases and controls

	Plasma Lycopene Mean±SD		
Fatty Acids	Cases	Controls	p-value
Trans-Lycopene	7.45±4.1	11.22±6.2	0.006
13-cis-Lycopene	4.11±2.4	4.52±3.2	0.57
9-cis-Lycopene A	0.97±1.5	1.13±1.0	0.67
9-cis-Lycopene B	1.53±1.2	1.53±1.6	0.99

Table 15. Comparison of fasting plasma Trans- and Cis- Lycopene (µg/dl)‡ of African-American prostate cancer cases and controls

	Plasma Lycopene Median (25^{th} , 75^{th} percentile)		
Fatty Acids	Cases	Controls	p-value
Trans-Lycopene	7.23 (3.99, 10.90)	10.79 (6.56, 15.56)	0.02
13-cis-Lycopene	3.84 (2.45, 5.23)	3.68 (2.59, 6.27)	0.83
9-cis-Lycopene A	0.42 (0.26, 0.85)	0.81 (0.29, 1.81)	0.22
9-cis-Lycopene B	1.54 (0.41, 2.29)	1.01 (0.49, 2.26)	0.62

Nigerians:

Table 16. Comparison of fasting plasma Trans- and Cis- Lycopene (µg/dl)‡ of Nigerian prostate cancer cases and controls

	Plasma Lycopene Mean±SD		
Fatty Acids	Cases	Controls	p-value
Trans-Lycopene	4.71±3.6	5.19±3.8	0.57
13-cis-Lycopene	3.02±1.8	4.95±3.2	0.002
9-cis-Lycopene A	0.57±0.4	0.80±0.7	0.08
9-cis-Lycopene B	1.16±0.9	1.74±1.2	0.02

Table 17. Comparison of fasting plasma Trans- and Cis- Lycopene (µg/dl)‡ of Nigerian prostate cancer cases and controls

	Plasma Lycopene Median (25^{th}, 75^{th} percentile)		
Fatty Acids	Cases	Controls	p-value
Trans-Lycopene	4.46 (1.21, 7.03)	4.33 (2.24, 5.94)	0.57
13-cis-Lycopene	2.67 (2.08, 4.31)	4.76 (2.40, 6.65)	0.004
9-cis-Lycopene A	0.57 (0.08, 0.84)	0.60 (0.37, 0.84)	0.23
9-cis-Lycopene B	1.14 (0.41, 1.87)	1.31 (0.96, 1.99)	0.03